REMARKS

The applicants have studied the final Office Action dated July 9, 2001, and respectfully requests entry of this response under the provisions of 37 C.F.R. § 1.116(a) in that the remarks below place the application and the claims in condition for allowance and in better form for consideration on appeal. By virtue of this response, claims 1-72 are pending, and no claims have been amended. Reconsideration and allowance of all of the claims in view of the following remarks are respectfully requested.

Embodiments of the present invention are directed to an external infusion device for infusion of a liquid into a body of a user. As disclosed, the claimed embodiments of the external infusion device may be worn on the exterior of the body under clothing, and may include, but is not limited to, an RF programming capability, a carbohydrate (or bolus) estimation capability, and/or vibration alarm capability, either alone or in combination. The disclosures of the Matsumura and the DeCant, Jr. et al. references are very different and are directed to implantable infusion pumps that are implanted under the skin in the body of a user, as will be discussed in detail below. Therefore, prior to a specific discussion of the differences between the Matsumura and the DeCant, Jr. et al. reference and the claims, the applicants will discuss the general structural differences between of the Matsumura and the DeCant, Jr. et al. implantable infusion pumps and prior art external infusion devices.

The Matsumura and DeCant, Jr. et al. implantable pumps are only utilized once they are implanted in the body under the skin. There are strong differences between the environment in which external infusion devices and implantable pumps operate. The pumps are substantially different in structure, function and appearance (see fig. 1 showing a prior art external infusion device and Fig. 2 showing an implantable infusion pump).

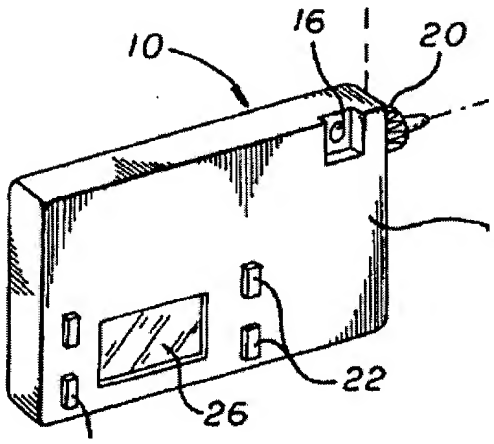

Fig. 1

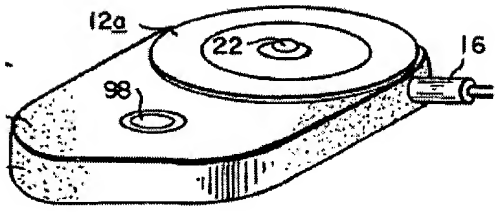

Fig. 2

Since prior art external infusion devices are worn on the outside of the body and are easily accessible, prior art external infusion devices often include a keyboard and a display built into the device to facilitate programming, control and review of information in the external infusion device. Other simple prior art external infusion devices may just have activation switches and/or may use tabs to program the external infusion devices. Thus, prior art external infusion devices actually teach away from the use of receiving remotely generated commands, since these devices already have a display and a keyboard (or activation switches and/or program tabs) on the external infusion device so that a remote programmer and/or remote generation of commands is not required. Also, the addition of a remote programmer and/or using remotely generated commands would increase the overall complexity and cost of the prior art external infusion devices, since the remote programmer would have to be added and the prior art external infusion device would require some modification to include a receiver.

Conversely, the implantable infusion pumps described in the Matsumura and DeCant, Jr. et al. references are designed to be placed under the skin of the user and do not include a display and a keyboard (or program tabs), since programming is carried out using a remote programming device. A remote programmer and or remotely generated commands are used to avoid having to pierce the skin to gain access to the programming features of the implantable infusion pump, thus avoiding pain and the chance of infection. Moreover, since implantable infusion pumps are

placed inside the body for long periods of time, they must be hermetically sealed against contaminates entering the device, and the present of displays or switches would generally make achieving these hermetic seals difficult and very costly.

Further, prior art external infusion devices are incapable of being implanted in the body of a patient. They are not sealed and would relatively quickly corrode in the presence of bodily fluids. In addition, prior art keypads, tabs, switches and displays would be generally inaccessible in the body. Also, prior art external infusion devices use disposable components that must be replaced every few days. Thus, a patient would require an invasive procedure every few days, which increase pain and the risk of infection.

Therefore, for implantable infusion pumps, a remote programmer and/or remotely generated commands are an absolute necessity unless the pump is programmed only once before it is fully implanted in the patient or if only a single switch is needed (such as on/off, or to switch operation modes). Thus, implantable infusion pumps teach and require a remote programmer and/or remotely generated commands to minimize pain and the chance of infection. This is specifically what is taught by the DeCant, Jr. et al. reference as stated by the Examiner (see col. 8, lines 53-59 and the instant Office Action at page 6, lines 7-15). On the other hand, prior art external infusion devices actually teach away from the use of a remote programmer and/or remotely generated commands due to redundancy, additional cost and increased complexity.

These are examples of only some aspects of the differences between implantable infusion pumps and external infusion devices, particularly as they relate to the remote programmers and programming. The specific differences related to the other features will be discussed below. But it is clear that the implantable pumps disclosed by the Matsumura and the DeCant, Jr. et al. references do not disclose, teach or suggest an external infusion device, a limitation that is specifically recited in all of the claims. Embodiments of the present invention are not disclosed, taught or suggested by implantable infusion pumps. Embodiments go beyond the teachings suggested by the prior art external infusion devices, by including new elements, such as, but not

limited to, an RF programming capability, a carbohydrate (or bolus) estimation capability, and/or vibration alarm capability, either alone or in combination. For instance, although not limited by this one example, since other specific features will be discussed below in the specific rejections, the remote commander can increase cost, but it can also increase convenience, flexibility and safety. Convenience is increased by allowing the user to cover the external infusion device under clothing, despite the need for programming various functions. Flexibility is increased, since the user can use the controls on-board the external infusion device for some programming and the remote commander for other commands or the remote commander for some of the same commands. Safety is increased, since some functions may be limited to the remote commander or the remote commander may be more accessible during an emergency. Design flexibility is also enhanced by either augmenting the existing elements on the external infusion device, such as the display, keypad, switches, tabs, or the like, allowing the removal of one or more of these elements or removing all of the elements from the external infusion device using the remote commander alone as taught in the specification. The claimed embodiments are not anticipated or obvious in view of the prior art. The only way to obtain the claimed embodiments is to use the applicants' specification as a template with impermissible hindsight.

The Examiner is impermissibly taking small bits and pieces from the references and connecting them together out of context to make them read upon the embodiments recited in the claims, despite contrary teachings in the reference when taken as a whole.

The applicants will now address each of the Examiner's rejections in turn. The specific differences between the claims and the references will be discussed and the references will be shown not to disclose, teach or suggest the embodiments recited in each claim.

Claims 1-13 were rejected under 35 U.S.C. § 102(b) as being anticipated by Matsumura 5,050,612. This rejection is respectfully traversed.

The Examiner starts the rejection by stating that the Matsumura reference "discloses a glucose sensor and insulin reservoir/pump on the body." However, this is not a correct characterization of the Matsumura reference as it relates to the claims. The Examiner has ignored a fundamental limitation in the claim to an external infusion device. In addition, the Matsumura "insulin reservoir/pump" is not on the body, but is instead actually in the body as is discussed in more detail below.

Claim 1 recites an "external infusion device for infusion of a liquid into a body, the external infusion device comprising: a housing; a receiver coupled to the housing for receiving remotely generated commands; a processor coupled to the housing and the receiver to receive remotely generated commands and to control the external infusion device in accordance with the commands; and an indication device to indicate when a command has been received and indicate when the command is being utilized to control the external infusion device such that the external infusion device is capable of being concealed from view on an individual when being remotely commanded" (emphasis added). Claim 11 recites similar language that recites the external infusion device can be concealed. The Matsumura reference does not disclose, teach or suggest an external infusion device capable of receiving remote commands and providing an indication of having received or utilized the commands and being capable of being concealed, as recited in claims 1 and 11.

The Matsumura reference is primarily directed to a computer-assisted monitoring system for patients, such as diabetics. The Matsumura reference does describe infusion pumps. But these infusion pumps are strictly implantable infusion pumps. The only fully disclosed infusion pump that will work with the Matsumura monitor is the one from Johns Hopkins University (see col. 13, lines 45-48). The Johns Hopkins' University infusion pumps are implantable infusion devices for use inside the body, and are cited in U.S. Patent Nos. 4,373,527, 4,494,950 and 4,731,051 to Fischell, which were disclosed in the May 11, 2000 Information Disclosure Statement filed in this application. None of these references describes external infusion devices. Although, the Matsumura reference does say other pumps are readily available from many

sources, none of these pumps are described as being external infusion devices. Thus, the Matsumura reference does not disclose, teach or suggest an external infusion device, as recited in claims 1 and 11.

The Examiner stated that the "infusion device is also capable of being concealed from view on an individual" when being remotely commanded. This is incorrect. The disclosed Matsumura pump is an implantable infusion pump, as discussed above. Accordingly, the Matsumura pump may only be concealed from view in an individual not on an individual. Implanted pumps are inside of a body not on the outside of a body.

The Examiner makes broad statements that it is "inherent that there is an indication device to indicate when a command has been received and indicate when the command is being utilized to control the external infusion device." This is incorrect. The Examiner has failed to show any teaching or disclosure in the Matsumura reference of an indication device on the disclosed infusion pumps or that the command has been received or is being utilized. In addition, assuming such an indication device were to exist on the implantable pump, the Examiner has not shown any teaching or suggestion on how that would be applicable to external infusion devices.

It is noted that the Cardiac Ischemia Monitor that is worn on the wrist may include a medication reservoir and a pump to infuse cardiac medications. However, this is part of the wrist monitor that communicates with the other devices and it is not disclosed or taught as being remotely programmable in any way (see col. 10, lines 20-40). Thus, this is not an external infusion device capable of receiving remote commands, as recited in the claims. In addition, since the monitor is worn on the wrist and must be accessible to communicate with the other devices, the medication reservoir would not be capable of being concealed from view on an individual, as recited in the claims.

Accordingly, the Matsumura reference does not disclose, teach or suggest the

embodiments of the external infusion device, as recited in claims 1 and 11.

Claim 2 is further distinguished from the Matsumura reference by reciting "wherein the external infusion device includes a memory for storing programs, and wherein the receiver is capable of receiving software updates and facilitating remote programming of external infusion device capabilities." Since the Matsumura reference does not disclose, teach or suggest an external infusion device, it does not disclose, teach or suggest an external infusion device that is remotely programmable or capable of receiving software updates, as recited in claim 2.

Claim 3 is further distinguished from the Matsumura reference by reciting "wherein the external infusion device includes a memory for storing a patient infusion history and pump activity" (emphasis added). The Matsumura reference does not disclose, teach or suggest a memory for storing a patient infusion history, as recited in claim 3. In fact, the sections of the Matsumura reference cited by the Examiner make no mention of the use of patient infusion histories. None of the memories included in the Matsumura infusion devices store patient infusion history, as recited in claim 3.

Claim 4 is further distinguished from the Matsumura reference by reciting "wherein the remotely generated commands are capable of programming and activating an audio bolus delivery of the liquid by the external infusion device" (emphasis added). The Examiner has cited no portion of the Matsumura reference that discloses, teaches or suggests a device where the remotely generated commands are capable of programming and activating an audio bolus delivery of the liquid by the external infusion device, as recited in claim 4. In fact, the sections of the Matsumura reference cited by the Examiner make no mention of the use of audio. There is no teaching or suggestion in the Matsumura reference of an audio device being used in conjunction with the administration of a bolus, as recited in the claim 4.

Claim 5 is further distinguished from the Matsumura reference by reciting "the remotely generated commands are capable of programming and activating a vibration bolus delivery of the

liquid by the external infusion device" (emphasis added). The Examiner has failed to cite any portion of the Matsumura reference that discloses, teaches or suggests a vibration bolus. The Matsumura reference contains no description of a vibration device. In fact, the sections of the Matsumura reference cited by the Examiner make no mention of the use of vibrations. Furthermore, the Matsumura reference does not teach or suggest the use of a vibration device in conjunction with a bolus delivery, as recited in the claim 5.

Claim 6 is further distinguished from the Matsumura reference by reciting "wherein the remotely generated commands are capable of programming and activating a temporary basal rate delivery of the liquid by the external infusion device" (emphasis added). Since the Matsumura reference does not disclose, teach or suggest an external infusion device, it does not disclose, teach or suggest an external infusion device with programming and activating a temporary basal rate, as recited in claim 6. Also, the Matsumura reference contains no description of a temporary basal rate. In fact, the sections of the Matsumura reference cited by the Examiner make no mention of the use of temporary basal rates.

Claim 7 is further distinguished from the Matsumura reference by reciting "wherein the remotely generated commands are capable of programming and suspending delivery of the liquid by the external infusion device." Since the Matsumura reference does not disclose, teach or suggest an external infusion device, it does not disclose, teach or suggest an external infusion device with programming and suspending delivery of the liquid, as recited in claim 7.

Claim 8 is further distinguished from the Matsumura reference by reciting "wherein the remotely generated commands are capable of programming and activating an extended bolus delivery of the liquid by the external infusion device" (emphasis added). Since the Matsumura reference does not disclose, teach or suggest an external infusion device, it does not disclose, teach or suggest an external infusion device with programming and activating an extended bolus, as recited in claim 8. Also, the Matsumura reference contains no description of an extended bolus. In fact, the sections of the Matsumura reference cited by the Examiner make no mention

of the use of an extended bolus.

Claim 9 is further distinguished from the Matsumura reference by reciting "the remotely generated commands are capable of programming and activating a dual wave bolus delivery of the liquid by the external infusion device" (emphasis added). The Examiner has cited no portion of the Matsumura reference that discloses, teaches or suggests a dual wave bolus delivery of liquid. Also, the Matsumura reference contains no description of a dual wave bolus. In fact, the sections of the Matsumura reference cited by the Examiner make no mention of the use of a dual wave bolus, as recited in claim 9.

Claim 10 is further distinguished from the Matsumura reference by reciting "wherein the remotely generated commands are capable of programming and activating a profiled bolus delivery of the liquid by the external infusion device" (emphasis added). Since the Matsumura reference does not disclose, teach or suggest an external infusion device, it does not disclose, teach or suggest an external infusion device with programming and activating a profiled bolus, as recited in claim 10. Also, the Matsumura reference contains no description of a profiled bolus. In fact, the sections of the Matsumura reference cited by the Examiner make no mention of the use of a profiled bolus.

Claim 11 has been distinguished as discussed above, and is further distinguished by the specific recitation of the remote commander structure and relationship related to the external infusion device. The Matsumura reference does not disclose, teach or suggest the remote commander and the relationship to the external infusion device, as recited in claim 11.

Claim 12 is further distinguished from the Matsumura reference by reciting "wherein the external infusion device further includes a device transmitter to verify receipt of commands from the remote commander, wherein the remote commander further includes a remote receiver to receive the verification from the device transmitter of the external infusion device, and wherein the remote commander further includes a remote indication device to indicate receipt of the

verification from the external infusion device." Since the Matsumura reference does not disclose, teach or suggest an external infusion device, it does not disclose, teach or suggest an external infusion device with a remote transmitter for communicating with a programmer having a receiver, as recited in claim 12. Also, the Matsumura reference contains no description of an external infusion device with a transmitter for communicating with a programmer having a receiver and an indication device. In fact, the sections of the Matsumura reference cited by the Examiner make no mention of the use of an external infusion device with a transmitter for communicating with a programmer having a receiver and an indication device.

Claim 13 is further distinguished from the Matsumura reference by reciting "wherein the remote commander is sized to fit on a key ring." The Matsumura reference discloses a wrist worn and sized monitor and transmitter that needs several straps to secure it to the wrist of the user. Also, the Matsumura reference contains no description of a remote commander on a key ring. In fact, the sections of the Matsumura reference cited by the Examiner make no mention of the use of a remote commander with a key ring.

Therefore, it is respectfully submitted that the rejection of claims 1-13 under 35 U.S.C. § 102(b) by the Matsumura reference should be withdrawn.

Claims 1-12, 20-43, 52-55, 58-64 and 70 were rejected under 35 U.S.C. § 102(b) as being anticipated by DeCant, Jr. et al. 4,443,218. This rejection is respectfully traversed.

The Examiner starts the rejection by stating that the DeCant, Jr. et al. reference "discloses a pump for delivery of insulin, wherein the pump has the ability to deliver at a wide range of bolus and basal flow rate, and allow programming allow a patient to set meal characteristics so that the bolus does can be tailored for each meals." However, this is not a correct characterization of the DeCant, Jr. et al. reference as it relates to the claims. The Examiner has picked and chosen selected phrases and words from the DeCant, Jr. et al. reference, and the Examiner has ignored a fundamental limitation in the claim to an external infusion device. In

addition, like the Matsumura device above, the "pump for delivery of insulin" is not on the body, but is instead actually in the body as is discussed in more detail below.

CLAIMS 1-12 and 20-35:

Claim 1 recites an "external infusion device for infusion of a liquid into a body, the external infusion device comprising: a housing; a receiver coupled to the housing for receiving remotely generated commands; a processor coupled to the housing and the receiver to receive remotely generated commands and to control the external infusion device in accordance with the commands; and an indication device to indicate when a command has been received and indicate when the command is being utilized to control the external infusion device such that the external infusion device is capable of being concealed from view on an individual when being remotely commanded" (emphasis added). Claim 11 recites similar language and recites that the external infusion device can be concealed. The DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device capable of receiving remote commands and providing an indication of having received or utilized the commands and being capable of being concealed, as recited in claims 1 and 11.

The DeCant, Jr. et al. reference is primarily directed to an implantable insulin pump for patients, such as diabetics. Thus, the DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device, as recited in claims 1 and 11.

The Examiner stated that the "means are provided for reprogramming the microprocessor to change the infusate flow schedule after the [implantable pump] is implanted in the body without having to invade the body." This is correct. The disclosed DeCant, Jr. et al. pump is an implantable infusion pump, as discussed above. Accordingly, the Examiner correctly points out that the DeCant, Jr. et al. pump may only be concealed from view in an individual not on an individual, which clearly fails to meet the claim limitation that the external infusion device is on the body. Implanted pumps are inside of a body not on the outside of a body.

The Examiner made a broad statement that it is "inherent that there is an indication device to indicate when a command has been received and indicate when the command is being utilized to control the external infusion device." This is not correct. The Examiner has failed to show any teaching or disclosure in the DeCant, Jr. et al. reference of an indication device on the disclosed infusion pumps or that an indication device may be used to indicate that a command has been received or is being utilized. In addition, assuming such an indication device were to exist on the implantable pump, the Examiner has not shown any teaching or suggestion on how that would be applicable to external infusion devices.

It is noted that the implantable infusion pump disclosed in the DeCant, Jr. et al. reference includes a switch 96 for changing from one flow rate to another flow rate (such as basal to bolus and back to a basal) so that a remote programmer is not required by the patient. However, the switch 96 is very limited in use, since the patient cannot change the programming or instructions contained in the implantable infusion pump. The patient is not programming the pump, but merely switching between preprogrammed operational modes to provide a higher rate of insulin during consumption of meals. In fact, the DeCant, Jr. et al. reference teaches that programming only occurs with a remote programmer used by the physician to effect major program changes and possibly a patient version that would allow the patient to select a certain bolus flow within a safe range that has been programmed by the physician (see col. 9, lines 8-17). Thus, the DeCant, Jr. et al. reference discloses and teaches an implantable infusion pump that is remotely programmable, but does not disclose teach or suggest an external infusion device or why or how the implantable pump programming would be applicable to external infusion devices, as recited in the claims. Thus, this is not an external infusion device capable of receiving remote commands, as recited in the claims.

Accordingly, the DeCant, Jr. et al. reference does not disclose, teach or suggest the embodiments of the external infusion device, as recited in claims 1 and 11.

Claim 2 is further distinguished from the DeCant, Jr. et al. reference by reciting "wherein the external infusion device includes a memory for storing programs, and wherein the receiver is capable of receiving software updates and facilitating remote programming of external infusion device capabilities." Since the DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device, it does not disclose, teach or suggest an external infusion device that is remotely programmable or capable of receiving software updates, as recited in claim 2.

Claim 3 is further distinguished from the DeCant, Jr. et al. reference by reciting "wherein the external infusion device includes a memory for storing a patient infusion history and pump activity" (emphasis added). The DeCant, Jr. et al. reference does not disclose, teach or suggest a memory for storing a patient infusion history in an external infusion device, as recited in claim 3.

Claim 4 is further distinguished from the DeCant, Jr. et al. reference by reciting "wherein the remotely generated commands are capable of programming and activating an audio bolus delivery of the liquid by the external infusion device" (emphasis added). The Examiner has cited no portion of the DeCant, Jr. et al. reference that discloses, teaches or suggests a device where the remotely generated commands are capable of programming and activating an audio bolus delivery of the liquid by the external infusion device, as recited in claim 4. In fact, the sections of the DeCant, Jr. et al. reference cited by the Examiner make no mention of the use of audio. There is no teaching or suggestion in the DeCant, Jr. et al. reference of an audio device being used in conjunction with the administration of a bolus, as recited in the claim 4.

Claim 5 is further distinguished from the DeCant, Jr. et al. reference by reciting "the remotely generated commands are capable of programming and activating a vibration bolus delivery of the liquid by the external infusion device" (emphasis added). The Examiner has failed to cite any portion of the DeCant, Jr. et al. reference that discloses, teaches or suggests a vibration bolus. The DeCant, Jr. et al. reference contains no description of a vibration device. In fact, the sections of the DeCant, Jr. et al. reference cited by the Examiner make no mention of the

use of vibrations. Furthermore, the DeCant, Jr. et al. reference does not teach or suggest the use of a vibration device in conjunction with a bolus delivery, as recited in the claim 5.

Claim 6 is further distinguished from the DeCant, Jr. et al. reference by reciting "wherein the remotely generated commands are capable of programming and activating a temporary basal rate delivery of the liquid by the external infusion device" (emphasis added). Since the DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device, it does not disclose, teach or suggest an external infusion device with programming and activating a temporary basal rate, as recited in claim 6. Also, although the DeCant, Jr. et al. reference does describe a basal flow, it does not disclose, teach or suggest multiple basal rates or the ability to program and activate a temporary basal rate. Also, the DeCant, Jr. et al. reference contains no description of a temporary basal rate. In fact, the sections of the DeCant, Jr. et al. reference cited by the Examiner make no mention of the use of temporary basal rates.

Claim 7 is further distinguished from the DeCant, Jr. et al. reference by reciting "wherein the remotely generated commands are capable of programming and suspending delivery of the liquid by the external infusion device." Since the DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device, it does not disclose, teach or suggest an external infusion device with programming and suspending delivery of the liquid, as recited in claim 7.

Claim 8 is further distinguished from the DeCant, Jr. et al. reference by reciting "wherein the remotely generated commands are capable of programming and activating an extended bolus delivery of the liquid by the external infusion device" (emphasis added). Since the DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device, it does not disclose, teach or suggest an external infusion device with programming and activating an extended bolus, as recited in claim 8. The DeCant, Jr. et al. reference does disclose switching to a bolus flow rate, but this does not equate to programming and activating an extended bolus. The Examiner has failed to cite any portion of the DeCant, Jr. et al. reference that discloses, teaches or suggests an extended bolus. Also, the DeCant, Jr. et al. reference contains no description of an extended

bolus.

Claim 9 is further distinguished from the DeCant, Jr. et al. reference by reciting "the remotely generated commands are capable of programming and activating a dual wave bolus delivery of the liquid by the external infusion device" (emphasis added). The Examiner has cited no portion of the DeCant, Jr. et al. reference that discloses, teaches or suggests a dual wave bolus delivery of liquid. Also, the DeCant, Jr. et al. reference contains no description of a dual wave bolus. In fact, the sections of the DeCant, Jr. et al. reference cited by the Examiner make no mention of the use of a dual wave bolus, as recited in claim 9.

Claim 10 is further distinguished from the DeCant, Jr. et al. reference by reciting "wherein the remotely generated commands are capable of programming and activating a profiled bolus delivery of the liquid by the external infusion device" (emphasis added). Since the DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device, it does not disclose, teach or suggest an external infusion device with programming and activating a profiled bolus, as recited in claim 10. The DeCant, Jr. et al. reference does disclose switching to a bolus flow rate, but it does not disclose, teach or suggest that this bolus can be profiled in any manner. The Examiner has failed to cite any portion of the DeCant, Jr. et al. reference that discloses, teaches or suggests a profiled bolus. Also, the DeCant, Jr. et al. reference contains no description of a profiled bolus.

Claim 11 has been distinguished as discussed above, and is further distinguished by the specific recitation of the remote commander structure and relationship related to the external infusion device. The DeCant, Jr. et al. reference does not disclose, teach or suggest the remote commander and the relationship to the external infusion device, as recited in claim 11.

Claim 12 is further distinguished from the DeCant, Jr. et al. reference by reciting "wherein the external infusion device further includes a device transmitter to verify receipt of commands from the remote commander, wherein the remote commander further includes a

remote receiver to receive the verification from the device transmitter of the external infusion device, and wherein the remote commander further includes a remote indication device to indicate receipt of the verification from the external infusion device." Since the DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device, it does not disclose, teach or suggest an external infusion device with a remote transmitter for communicating with a programmer having a receiver, as recited in claim 12. The Examiner has failed to cite any portion of the DeCant, Jr. et al. reference that discloses, teaches or suggests an external infusion device with a transmitter for communicating with a programmer having a receiver and an indication device. Also, the DeCant, Jr. et al. reference contains no description of an external infusion device with a transmitter for communicating with a programmer having a receiver and an indication device. In fact, the sections of the DeCant, Jr. et al. reference cited by the Examiner make no mention of the use of an external infusion device with a transmitter for communicating with a programmer having a receiver and an indication device.

Claim 20 is further distinguished from the DeCant, Jr. et al. reference by reciting "wherein the remote commander is capable of providing remote commands at a distance greater than 1 inch." The Examiner has cited no portion of the DeCant, Jr. et al. reference that discloses, teaches or suggests that a programmer can provide commands at a distance greater than 1 inch. Many implantables are placed just under the surface of the skin and the programmer is placed against the skin. Also, the DeCant, Jr. et al. reference contains no description of how the actual programming, let alone the distance, is performed. In fact, the sections of the DeCant, Jr. et al. reference cited by the Examiner make no mention of the use of the operating distance for a programmer, as recited in claim 20.

The Examiner rejected claims 21-22 by simply reciting back the limitations in the claims without a specific reference to where it is disclosed in the DeCant, Jr. et al. reference. Claim 21 is further distinguished from the DeCant, Jr. et al. reference by reciting "wherein the processor of the external infusion device has a unique identification code, and wherein the remote commander includes the capability to read and learn the unique identification code of the external infusion

device, and wherein the remote commander and the external infusion device use the unique identification code to substantially avoid interference with other external infusion devices," (emphasis added), and claim 22 similarly recites, "wherein the remote commander has a unique identification code, and wherein the processor of the external infusion device includes the capability to read and learn the unique identification code of the remote commander, and wherein the remote commander and the external infusion device use the unique identification code to substantially avoid interference with other remote commanders" (emphasis added). The Examiner has cited no portion of the DeCant, Jr. et al. reference that discloses, teaches or suggests an external infusion device that has a unique identification code that can be read by a remote commander, or a remote commander that has a unique identification code that can be read by an external infusion device, as recited in the claims. The DeCant, Jr. et al. reference does not disclose, teach or suggest the additional feature of an identification code to prevent interference in any of its embodiments.

Claim 23 is further distinguished from the DeCant, Jr. et al. reference by reciting "wherein the remote commander includes a mode that permits physician controlled programming of specific capabilities of the external infusion device to the exclusion of the user." Since the DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device, it does not disclose, teach or suggest an external infusion device with a remote programmer, as recited in claim 23. Furthermore, the DeCant, Jr. et al. reference does not disclose, teach or suggest a remote commander that includes a mode that permits the exclusion of the user, as recited in the claim.

Claim 24 is further distinguished from the DeCant, Jr. et al. reference by reciting "wherein the remote commander may also include a link to a computer to allow computer programming to initiate or alter available capabilities of the external infusion device." Since the DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device, it does not disclose, teach or suggest an external infusion device with a link to allow computer programming or altering capabilities, as recited in claim 24.

Claim 25 is further distinguished from the DeCant, Jr. et al. reference by reciting "wherein the external infusion device includes a memory for storing programs, and wherein the receiver is capable of receiving software updates to facilitate remote programming of external infusion device capabilities." Since the DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device, it does not disclose, teach or suggest an external infusion device with a memory for storing programs and the capability to receive software updates, as recited in claim 25. In addition, the DeCant, Jr. et al. reference only discloses changing flow rates, and does not disclose, teach or suggest the ability to update software for either remote programming or any other purpose.

Claims 26 and 27 are further distinguished over the DeCant, Jr. et al. reference by reciting "wherein the remote commander is capable of receiving data from another medical device and relaying the received data to the external infusion device," and furthermore, "the remote commander is capable of remotely commanding and controlling the other medical device." The Examiner has cited no portion of the DeCant, Jr. et al. reference, which teaches or suggests a remote commander capable of receiving data from another medical device and relaying the data to the external infusion device, as recited in claim 26. Nor has the Examiner cited a portion of the DeCant Jr. et al. reference, which further teaches or suggests a remote commander that could also remotely command and control the other medical device, as recited in the claims. The DeCant Jr. et al. reference does not teach or suggest the additional feature of a device that is capable of programming an external infusion pump and also communicating with and/or commanding and controlling another device, as recited in claims 26 and 27.

Claims 28 and 29 are further distinguished over the DeCant, Jr. et al. reference by reciting "wherein the remote commander is capable of programming and activating an audio bolus delivery of the liquid by the external infusion device," and "wherein the remote commander is capable of programming and activating a vibration bolus delivery of the liquid by the external infusion device," (emphasis added). As discussed with respect to claims 4 and 5 above, the

Examiner has cited no portion of the DeCant, Jr. et al. reference that discloses, teaches or suggests a remote commander that is capable of programming and activating an audio bolus or a vibration bolus delivery of the liquid by the external infusion device, as recited in claims 28 and 29.

Claim 30 is further distinguished from the DeCant, Jr. et al. reference by reciting "wherein the remote programmer is capable of programming and activating a temporary basal rate delivery of the liquid by the external infusion device" (emphasis added). Since the DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device, it does not disclose, teach or suggest an external infusion device with programming and activating a temporary basal rate, as recited in claim 30. Also, although the DeCant, Jr. et al. reference does describe a basal flow, it does not disclose, teach or suggest multiple basal rates or the ability to program and activate a temporary basal rate. Also, the DeCant, Jr. et al. reference contains no description of a temporary basal rate. In fact, the sections of the DeCant, Jr. et al. reference cited by the Examiner make no mention of the use of temporary basal rates.

Claim 31 is further distinguished from the DeCant, Jr. et al. reference by reciting "wherein the remote programmer is capable of programming and suspending delivery of the liquid by the external infusion device." Since the DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device, it does not disclose, teach or suggest an external infusion device with programming and suspending delivery of the liquid, as recited in claim 31.

Claim 32 is further distinguished from the DeCant, Jr. et al. reference by reciting "wherein the remote programmer is capable of programming and activating an extended bolus delivery of the liquid by the external infusion device" (emphasis added). Since the DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device, it does not disclose, teach or suggest an external infusion device with programming and activating an extended bolus, as recited in claim 32. The DeCant, Jr. et al. reference does disclose switching to a bolus flow rate, but this does not equate to programming and activating an extended bolus. The Examiner

has failed to cite any portion of the DeCant, Jr. et al. reference that discloses, teaches or suggests an extended bolus. Also, the DeCant, Jr. et al. reference contains no description of an extended bolus. In fact, the sections of the DeCant, Jr. et al. reference cited by the Examiner make no mention of the use of an extended bolus.

Claim 33 is further distinguished from the DeCant, Jr. et al. reference by reciting "wherein the remote programmer is capable of programming and activating a profiled bolus delivery of the liquid by the external infusion device" (emphasis added). Since the DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device, it does not disclose, teach or suggest an external infusion device with programming and activating a profiled bolus, as recited in claim 33. The DeCant, Jr. et al. reference does disclose switching to a bolus flow rate, but it does not disclose, teach or suggest that this bolus can be profiled in any manner. The Examiner has failed to cite any portion of the DeCant, Jr. et al. reference that discloses, teaches or suggests a profiled bolus. Also, the DeCant, Jr. et al. reference contains no description of a profiled bolus. In fact, the sections of the DeCant, Jr. et al. reference cited by the Examiner make no mention of the use of a profiled bolus.

Claim 34 is further distinguished from the DeCant, Jr. et al. reference by reciting "the remote programmer is capable of programming and activating a dual wave bolus delivery of the liquid by the external infusion device" (emphasis added). The Examiner has cited no portion of the DeCant, Jr. et al. reference that discloses, teaches or suggests a dual wave bolus delivery of liquid. Also, the DeCant, Jr. et al. reference contains no description of a dual wave bolus. In fact, the sections of the DeCant, Jr. et al. reference cited by the Examiner make no mention of the use of a dual wave bolus, as recited in claim 34.

Accordingly, it is respectfully submitted that claims 1-12 and 20-35 are not anticipated under 35 U.S.C. § 102(b) by the DeCant, Jr. et al. reference.

CLAIMS 35-43:

The Examiner has cited no portion of the DeCant, Jr. et al. reference that in any manner teaches or suggests the embodiments recited in claims 35-43. For example, claim 35 recites an "external infusion device for infusion of a liquid into a body, the external infusion device comprising: a housing, a processor coupled to the housing, a bolus estimator used in conjunction with the processor and externally supplied values to estimate an amount of liquid to be infused based upon an estimate of a material to be ingested by the body; and an indication device to indicate when an amount of fluid to be infused has been calculated" (emphasis added). The DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device that includes a bolus estimator used to estimate an amount of liquid to be infused based upon an estimate of a material to be ingested by the body. Thus, the DeCant, Jr. et al. reference does not disclose, teach or suggest a bolus estimator using an estimate of ingested material, as recited in claim 35.

The DeCant, Jr. et al. reference does describe that the patient can tailor the bolus rate to match the characteristics of the meal, as shown at col. 2, lines 39-42. However, it is clear from the description at col. 5, lines 55-59 and col. 8, lines 47-48 and 53-63 that this accomplished solely by the use of a switch 96, or a limited patient programmer, that lets the patient only switch between a basal flow rate and a bolus flow rate (see col. 8, line 64 to col. 9, line 17). Thus, the patient must manually switch or command the implantable pump to change flow rates to deliver a desired bolus amount. There is no disclosure, teaching or suggestion anywhere in the DeCant, Jr. et al. reference of the implantable pump calculating the time of or the size of the bolus delivery. It is all up to the patient to determine by approximation or determination without the aid any feature contained in the implantable pump. Also, there is no disclosure, teaching or suggestion of the implantable pump providing an estimate. Furthermore, there is no description of an estimate from an internal implantable infusion pump could be made available to a user. Conversely, the claimed bolus estimator uses the processor and externally supplied values to estimate the amount of liquid to be infused. Thus, the patient need not guess how much fluid is needed, the external infusion device performs the calculation and provides that information to the

patient. Therefore, the DeCant, Jr. et al. implantable pump is fundamentally different, since it requires the patient to determine when to start and end the bolus rate, while the claimed bolus estimator determines an estimate based on various values supplied to the external infusion device processor and informs the patient what amount of fluid should be infused.

Dependent claims 36, 37, and 40 are further distinguished from the DeCant, Jr. et al reference by reciting specific additional features of the bolus estimator that are not disclosed, taught, or suggested in the DeCant, Jr. et al. reference. The Examiner has cited, no portion of the DeCant, Jr. et al. reference that teaches or suggests an external infusion device with a bolus estimator that includes "the capability to calculate a correction bolus based upon a current characteristic value and a target characteristic value," as recited in claim 36, or "a liquid sensitivity that is used to determine the amount of liquid to be infused to calculate the correction bolus," as recited in claim 37, or "a lockout to prevent the calculation of a bolus for a predetermined period of time after a bolus is estimated by the bolus estimator," as recited in claim 40. The Examiner makes broad statements that these elements are disclosed in the DeCant, Jr. et al. reference, but this is simply not the case and the sections specifically cited by the Examiner do not contain any language that could be construed to cover these elements.

Claims 38 and 39 are further distinguished over the DeCant, Jr. et al. reference by reciting "the liquid to be infused is insulin" and "where the material to be ingested is carbohydrates," respectively. While the DeCant, Jr. et al. implantable pump may be used for insulin pumps, there is no teaching or suggestion in the DeCant, Jr. et al. reference of the additional feature of a device to estimate an amount of insulin to be infused based upon an estimate of carbohydrates to be ingested by the body, as recited in claims 38 and 39.

Claims 41 and 42 are further distinguished over the DeCant, Jr. et al. reference by reciting that the supplied values used in conjunction with the a bolus estimator and the processor are "codes representing a carbohydrate value of specific foods" or "codes representing a carbohydrate value of specific meals," respectively. The DeCant, Jr. et al. reference does not

teach or suggest the additional feature of a device with a bolus estimator that accepts codes representing a carbohydrate value of foods or meals, as recited in claims 41 and 42.

Claim 43 is further distinguished over the DeCant, Jr. et al. reference by reciting that the external infusion device further includes "a duration factor to determine a value of how long a previously infused amount of liquid will remain active in the body, wherein the determined value is used to adjust the amount of the fluid to be infused" (emphasis added). Thus, the Examiner has cited no portion of the DeCant, Jr. et al. reference that teaches or suggests the additional feature of a duration factor to adjust the amount of the fluid to be infused.

Accordingly, it is respectfully submitted that claims 35-43 are not anticipated under 35 U.S.C. § 102(b) by the DeCant, Jr. et al. reference.

CLAIMS 52 and 53:

Claims 52 and 53 recite an "external infusion device for infusion of a liquid into a body, the external infusion device comprising: a housing, a processor coupled to the housing, ...a memory coupled to and used in conjunction with the processor to store at least two personal delivery patterns, ... an indication device to indicate the selected personal delivery pattern, wherein the processor controls the external infusion device in accordance with the selected one of the at least two personal delivery patterns" (emphasis added). The DeCant, Jr. et al. reference does not teach or suggest an external infusion device or a memory to store at least two personal delivery patterns, as recited in the claims. Thus, values for only one set of parameters are stored for the single flow rate pattern used by the patient, and the DeCant, Jr. et al. reference does not teach or suggest a memory to store at least two personal delivery patterns, as recited in claims 52 and 53.

In addition, the ability to switch between bolus and basal rates is not the same as the at least two personal delivery patterns recited in the claims. There is no pattern, since one merely switches between two different rates. Also, there is no disclosed indication device for providing

an indication when the implantable pump is switched between the rates with switch 96. Furthermore, the patient external programmer is not disclosed as including an indication device, as recited in the claims. Moreover, there is no disclosure, teaching or suggestion of at least two delivery patterns being stored in the memory of an implantable pump.

Accordingly, it is respectfully submitted that claims 52 and 53 are not anticipated under 35 U.S.C. § 102(b) by the DeCant, Jr. et al. reference.

CLAIM 54:

Claim 54 recites an "external infusion device for infusion of a liquid into a body, the external infusion device comprising:...a memory coupled to and used in conjunction with the processor to store at least two basal rate profiles, a keypad coupled to the housing and used in conjunction with the processor to program the at least two basal rate profiles, and an indication device to indicate the basal rate profiles during programming, wherein the processor controls the external infusion device in accordance with the programmed at least two basal rate profiles" (emphasis added). The DeCant, Jr. et al reference only describes and discloses a single basal rate that is stored in the memory of the implantable pump. Thus, the DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device including a memory to store at least two basal rate profiles, as recited in claim 54.

In addition, the ability to switch between bolus and basal rates is not the same as the at least two basal profiles recited in the claims. There is no profile, since one merely switches between two different rates. Also, there is no disclosed indication device for providing an indication when the implantable pump is switched between the rates with switch 96. Furthermore, the patient external programmer is not disclosed as including an indication device, as recited in the claims. Moreover, there is no disclosure, teaching or suggestion of at least two basal profiles being stored in the memory of the implantable pump.

Accordingly, it is respectfully submitted that claim 54 is not anticipated under 35 U.S.C.

§ 102(b) by the DeCant, Jr. et al. reference.

CLAIM 55:

Claim 55 recites an "external infusion device for infusion of a liquid into a body, the external infusion device comprising: a housing, a processor coupled to the housing, a memory coupled to and used in conjunction with the processor to store at least two bolus types, a keypad coupled to the housing and used in conjunction with the processor to select one of the at least two bolus types, and an indication device to indicate the selected bolus type, wherein the processor controls the external infusion device in accordance with the selected one of the at least two bolus types" (emphasis added). The DeCant, Jr. et al. reference only describes and discloses a single bolus rate that is stored in the memory of the implantable pump. Thus, the DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device including a memory to store at least two bolus types, as recited in claim 55.

In addition, the ability to switch between bolus and basal rates is not the same as the at least two bolus types recited in the claims. There is no pattern, since one merely switches between two different rates. Also, there is no disclosed indication device for providing an indication when the implantable pump is switched between the rates with switch 96. Furthermore, the patient external programmer is not disclosed as including an indication device, as recited in the claims. Moreover, there is no disclosure, teaching or suggestion of at least two bolus types being stored in the memory of the implantable pump.

Accordingly, it is respectfully submitted that claim 55 is not anticipated under 35 U.S.C. § 102(b) by the DeCant, Jr. et al. reference.

CLAIMS 58-64 and 70

Claim 58 is further distinguished by reciting an infusion system comprising, "a remote commander including...a transmitter coupled to the keypad for wirelessly transmitting commands to the receiver of the external infusion device, wherein the remote commander is

portable," (emphasis added). The DeCant, Jr. et al. reference does not disclose, teach or suggest an infusion system with a remote commander that has a transmitter for wirelessly transmitting commands to the receiver of the external infusion device, and where the remote commander is portable. Since the DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device, it does not disclose, teach or suggest an external infusion device with a wirelessly transmitting, portable remote programmer, as recited in claim 58.

Claim 59 is further distinguished by reciting an infusion system comprising a remote commander "wherein the remote commander is one or more remote commanders and each of the one or more remote commanders includes: a commander housing, a keypad coupled to the commander housing for inputting commands, and a transmitter coupled to the keypad for wirelessly transmitting commands to the receiver of the external infusion device" (emphasis added). Since the DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device, it does not disclose, teach or suggest an external infusion device with one or more remote programmers, as recited in claim 59.

Claim 60 is further distinguished by reciting "wherein the one or more remote commanders each have a unique identification code, and wherein the processor of the external infusion device includes the capability to store the unique identification codes of the one or more remote commanders, and wherein the one or more remote commanders and the external infusion device use the unique identification codes to substantially avoid interference with other remote commanders" (emphasis added). The DeCant, Jr. et al. reference does not disclose, teach or suggest the use of remote commanders each with a unique identification code that the external infusion device stores and uses to substantially avoid interference with other remote commanders. The DeCant, Jr. et al. reference does not teach or suggest that access codes may be used in any way to avoid interference with other remote commanders, and furthermore, the access codes of the DeCant, Jr. et al. reference are not unique to individual remote commanders, as recited in claim 60.

Claim 61 is further distinguished by reciting "wherein the external infusion device is programmable to store one or more identification codes, wherein each remote commander transmits an identification code, and wherein the external infusion device only responds to commands sent from a remote commander that transmits an identification code that has been programmed into the external infusion device" (emphasis added). The DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device that is programmable to store one or more identification codes and will only respond to commands sent from a remote commander that transmits an identification code that has been programmed, as recited in claim 61.

Claim 62 is further distinguished by reciting "wherein the remote commander establishes non-line of sight communication with the external infusion device." Since the DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device, it does not disclose, teach or suggest an external infusion device with a remote commander that establishes non-line of sight communication with the external infusion device as recited in claim 62.

Claim 63 is further distinguished by reciting an external infusion device including a receiver for receiving remotely generated commands "wherein the receiver includes a standby mode, and wherein while the receiver is in the standby mode the receiver does not receive." Since the DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device, it does not disclose, teach or suggest an external infusion device with a receiver that does not receive while in a standby mode, as recited in claim 63.

Claim 64 is further distinguished by reciting an external infusion device including a receiver for receiving remotely generated commands, ...wherein while the receiver is in the standby mode the receiver does not receive and, "wherein the receiver periodically becomes active to see if the transmitter is transmitting" (emphasis added.). Since the DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device, it does not disclose, teach or suggest an external infusion device with a receiver that periodically becomes active to

see if a transmitter is transmitting, as recited in claim 64.

Claim 70 is further distinguished by reciting an external infusion device including a processor to store at least two personal delivery patterns "wherein the at least two personal delivery patterns are programmable by a user," (emphasis added). As discussed previously, the DeCant, Jr. et al. reference does not teach or suggest a memory to store at least two personal delivery patterns, as recited in the claims. Since the DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device, it does not disclose, teach or suggest an external infusion device where the at least two personal delivery patterns are programmable by the user, as recited in claim 70. Only, the physician programmer is disclosed as be able to do programming. The DeCant, Jr. et al. reference does not teach or suggest a memory to store at least two personal delivery patterns, as recited in the claims. Thus, values for only one set of parameters are stored for the single flow rate pattern used by the patient, and the DeCant, Jr. et al. reference does not teach or suggest a memory to store at least two personal delivery patterns, as recited in claim 70.

Therefore, it is respectfully submitted that the rejection of claims 1-12, 20-43, 52-55, 58-64 and 70 under 35 U.S.C. § 102(b) by the DeCant, Jr. et al. reference should be withdrawn.

Claims 14 and 16 were rejected under 35 U.S.C. § 103(a) as being unpatentable over by DeCant, Jr. et al. 4,443,218 in view of Bentsen et al. 6,009,339. This rejection is respectfully traversed.

Claims 14 and 16 depend from claim 11, which as discussed above is patentably distinguished over the DeCant, Jr. et al. reference. Therefore, claims 14 and 16 are also patentably distinguished over the DeCant, Jr. et al. reference for the same reasons.

The Bentsen et al. reference does not make up for the deficiencies of the DeCant, Jr. et al. reference. The Bentsen et al. reference is directed to a blood parameter measuring device and does not disclose, teach or suggest external infusion devices or how features from implantable pumps could be applied to external infusion devices, as recited in the claims.

Claim 14 is further distinguished over the DeCant, Jr. et al. reference and the Bentsen et al. reference by reciting "wherein the remote commander uses RF frequencies to transmit remote commands to the external infusion device." Since the DeCant, Jr. et al. reference and the Bentsen et al. reference do not disclose, teach or suggest an external infusion device, they do not disclose, teach or suggest an external infusion device with a remote commander that uses RF frequencies, as recited in claim 14.

Claim 16 is further distinguished over the DeCant, Jr. et al. reference and the Bentsen et al. reference by reciting "wherein the remote commander uses optical frequencies to transmit remote commands to the external infusion device." Since the DeCant, Jr. et al. reference and the Bentsen et al. reference do not disclose, teach or suggest an external infusion device, they do not disclose, teach or suggest an external infusion device with a remote programmer that uses optical frequencies, as recited in claim 16. In addition, since the DeCant, Jr. et al. implantable pump is implanted under the skin of the user, optical frequencies will not work and the DeCant, Jr. et al. reference actually teaches away from the use of optical frequencies.

Therefore, it is respectfully submitted that the rejection of claims 14 and 16 under 35 U.S.C. § 103(a) by the DeCant, Jr. et al. reference and the Bentsen reference should be withdrawn.

Claim 15 was rejected under 35 U.S.C. § 103(a) as being unpatentable over by DeCant, Jr. et al. 4,443,218 in view of Dempsey et al, 5,687,734. This rejection is respectfully traversed.

Claim 15 depends from claim 11, which as discussed above is patentably distinguished over the DeCant, Jr. et al. reference. Therefore, claim 15 is also patentably distinguished over the DeCant, Jr. et al. reference for the same reasons.

The Dempsey et al. reference does not make up for the deficiencies of the DeCant, Jr. et al. reference. The Dempsey et al. reference is directed to a patient monitoring system for a telemetry network in a hospital and does not disclose, teach or suggest external infusion devices or how features from implantable pumps could be applied to external infusion devices, as recited in the claims.

Claim 15 is further distinguished over the DeCant, Jr. et al. reference and the Dempsey et al. reference by reciting "wherein the remote commander uses IR frequencies to transmit remote commands to the external infusion device." Since the DeCant, Jr. et al. reference and the Dempsey et al. reference do not disclose, teach or suggest an external infusion device, they do not disclose, teach or suggest an external infusion device with remote programmer that uses IR frequencies, as recited in claim 15. In addition, since the DeCant, Jr. et al. implantable pump is implanted under the skin of the user, IR frequencies will not work and the DeCant, Jr. et al. reference actually teaches away from the use of IR frequencies.

Therefore, it is respectfully submitted that the rejection of claim15 under 35 U.S.C. § 103(a) by the DeCant, Jr. et al. reference and the Dempsey et al. reference should be withdrawn.

Claims 17 and 18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over by DeCant, Jr. et al. 4,443,218 in view of Feierbach 5,861,018. This rejection is respectfully traversed.

Claims 17 and 18 depend from claim 11, which as discussed above is patentably distinguished over the DeCant, Jr. et al. reference. Therefore, claims 17 and 18 are also patentably distinguished over the DeCant, Jr. et al. reference for the same reasons.

The Feierbach reference does not make up for the deficiencies of the DeCant, Jr. et al. reference. The Feierbach reference is directed to an external transdermal communication device that communicates with an implanted medical communication device and does not disclose, teach or suggest external infusion devices or how features from implantable pumps could be applied to external infusion devices, as recited in the claims.

Claim 17 is further distinguished over the DeCant, Jr. et al. reference and the Feierbach reference by reciting "wherein the remote commander uses ultrasonic frequencies to transmit remote commands to the external infusion device." Since the DeCant, Jr. et al. reference and the Feierbach do not disclose, teach or suggest an external infusion device, they do not disclose, teach or suggest an external infusion device with a remote programmer that uses ultrasonic frequencies, as recited in claim 17.

Claim 18 is further distinguished over the DeCant, Jr. et al. reference and the Feierbach reference by reciting "wherein the remote commander uses audio frequencies to transmit remote commands to the external infusion device." Since the DeCant, Jr. et al. reference and the Feierbach reference do not disclose, teach or suggest an external infusion device, they do not disclose, teach or suggest an external infusion device with a remote programmer that uses ultrasonic frequencies, as recited in claim 18.

Therefore, it is respectfully submitted that the rejection of claims 17 and 18 under 35 U.S.C. § 103(a) by the DeCant, Jr. et al. reference and the Feierbach reference should be withdrawn.

Claim 19 was rejected under 35 U.S.C. § 103(a) as being unpatentable over by DeCant, Jr. et al. 4,443,218 in view of Batina et al. 4,550,731. This rejection is respectfully traversed.

Claim 19 depends from claim 11, which as discussed above is patentably distinguished over the DeCant, Jr. et al. reference. Therefore, claim 19 is also patentably distinguished over the DeCant, Jr. et al. reference for the same reasons.

The Batina et al. reference does not make up for the deficiencies of the DeCant, Jr. et al. reference. The Batina et al. reference is directed to a communication device for an implanted cardiac pacemaker and does not disclose, teach or suggest external infusion devices or how features from implantable pumps could be applied to external infusion devices, as recited in the claims.

Claim 19 is further distinguished over the DeCant, Jr. et al. reference and the Batina et al. reference by reciting "wherein the remote commander uses magnetic effects to transmit remote commands to the external infusion device." Since the DeCant, Jr. et al. reference and the Batina et al. reference do not disclose, teach or suggest an external infusion device, they do not disclose, teach or suggest an external infusion device with a remote programmer that uses magnetic effects, as recited in claim 19.

Therefore, it is respectfully submitted that the rejection of claim19 under 35 U.S.C. § 103(a) by the DeCant, Jr. et al. reference and the Batina et al. reference should be withdrawn.

Claims 44-50 were rejected under 35 U.S.C. § 103(a) as being unpatentable over by DeCant, Jr. et al. 4,443,218 in view of Dent, 5,609,060. This rejection is respectfully traversed.

Claims 44-50 are further distinguished over the DeCant, Jr. et al. reference by claiming unique applications or uses for the vibration alarm. Claims 44-46 state that the vibration alarm is used to, "remove gas bubbles from the fluid in the reservoir during priming," "agitate fluid in the reservoir between successive delivery periods," or "agitate the fluid in the reservoir during delivery," respectively. Claims 48 and 49 recite similar language. Claim 47 recites, " a vibration alarm used in conjunction with the processor and the audible alarm." And claim 50 recites that,

"the processor selects to activate one of the audible alarm and vibration alarm independently." The DeCant, Jr. et al. reference does not disclose, teach, or suggest uses for a vibration alarm alone, or in conjunction with an audible alarm, as recited in claims 44-50.

The Dent reference does not make up for the deficiencies of the DeCant, Jr. et al. reference. The Dent reference is directed to a multiple channel manometer apparatus to provide information regarding the function of the digestive tract in animals and children. The device uses water and carbon dioxide. This is an external type of pump, but it is not capable of being concealed. There is also no teaching or suggestion that the disclosed techniques could be applied to implantable pumps or devices concealed on the body. In addition, the Dent reference does not disclose, teach or suggest external infusion devices or how features from implantable pumps could be applied to external infusion devices, as recited in the claims.

Therefore, it is respectfully submitted that the rejection of claims 44-50 under 35 U.S.C. § 103(a) by the DeCant, Jr. et al. reference and the Dent reference should be withdrawn.

Claims 51, 56, 57 and 65-69 were rejected under 35 U.S.C. § 103(a) as being unpatentable over by DeCant, Jr. et al. 4,443,218. This rejection is respectfully traversed.

Claim 51 recites, "An external infusion device for infusion of a liquid into a body, the external infusion device comprising: a housing, a processor coupled to the housing, a keypad coupled to the housing and used in conjunction with the processor to determine an estimate of remaining battery power, and an indication device to indicate the estimate of remaining battery power" (emphasis added). The DeCant, Jr. et al. reference does not disclose teach or suggest the use of a keypad coupled to the housing of the infusion device to determine an estimate of remaining battery power. It has no keypad – at best only a single switch 96. The DeCant, Jr. et al. reference does not teach or suggest a device to estimate the remaining battery power, nor does it teach or suggest an indication device to indicate the estimate of the remaining battery power, as recited in claim 51.

Claims 56 and 57 depend from claim 1, which as discussed above is patentably distinguished over the DeCant, Jr. et al. reference. Therefore, claims 56 and 57 are also patentably distinguished over the DeCant, Jr. et al. reference for the same reasons.

Claim 56 is further distinguished by reciting "an indication device to indicate when a command has been received and indicate when the command is being utilized to control the external infusion device, wherein the indication device produces an audible indication" (emphasis added). The DeCant, Jr. et al. reference does not disclose, teach or suggest an infusion device with an indication device that that produces an audible indication that a command has been received or to indicate when a command is being used to control an external infusion device. The DeCant, Jr. et al. reference does not teach or show that an internal audio device is used to indicate that the command has been received or that a command is being used by an external infusion device.

Claim 57 is further distinguished by reciting "an indication device to indicate when a command has been received and indicate when the command is being utilized to control the external infusion device, wherein the indication device produces a vibratory indication," (emphasis added). The DeCant, Jr. et al. reference does not disclose, teach or suggest an infusion device with an indication device that produces a vibratory indication that a command has been received or to indicate when a command is being used to control an external infusion device.

Claim 65 is distinguished from the DeCant, Jr. et al. reference by reciting an "external infusion device for infusion of a liquid into a body of a user, the external infusion device comprising: a housing containing a reservoir, a processor coupled to the housing, and a vibration alarm used in conjunction with the processor to provide one or more tactile sensations to a user," (emphasis added). The DeCant, Jr. et al. reference does not disclose, teach or suggest a vibration alarm to provide tactile sensations to a user.

Claims 66-69 are further distinguished over the DeCant, Jr. et al. reference by virtue of including a vibration alarm as discussed above, and serve to further describe embodiments of the present invention.

Therefore, it is respectfully submitted that the rejection of claims 51, 56, 57 and 65-69 under 35 U.S.C. § 103(a) by the DeCant, Jr. et al. reference should be withdrawn.

Claims 71 and 72 were not rejected in the present Office Action. Claims 71 and 72 are distinguished over the Matsumura and the DeCant, Jr. et al. references, by virtue of arguments presented earlier that the Matsumura and the DeCant, Jr. et al. references, do not teach or suggest the use of two or more personal delivery patterns. Claims 71 and 72 serve to further define embodiments of the present invention. The applicants respectfully submit that claims 71 and 72 do not read on the Matsumura and the DeCant, Jr. et al. references and are in condition for allowance.

In view of the foregoing, it is respectfully submitted that the application and all of the claims are in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is invited to call the undersigned attorney at (818) 576-5313 should the Examiner believe a telephone interview would advance the prosecution of the application.

Respectfully submitted,

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By: _____

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